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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,381	01/15/2004	Raphael J. Mannino	BSZ-017	6695

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,381	MANNINO ET AL.	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *11,12,17,18,21-28,30, 31 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-16,19,20,29 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/01/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Information disclosure statement dated 07/01/2005 is acknowledged.

Election/Restrictions

1. Applicant's election without traverse of Group I claims 1-20, and 29-37 in the reply filed on 1/4/08 is acknowledged. Applicant's election of species of phytochemical (beta-carotene), a cargo moiety (vitamin) and a product (skin care product). For clarification, The Examiner required a restriction/election requirement and further explained the requirement in a communications dated 12/13/07. Accordingly, claims 11, 12 (zoochemical) and claims 17, 18, 30 and 31 (food product) are withdrawn from consideration. The election is made without traverse.

Status of Claims: in view of Appicant's election claims 1-10, 13-16, 19-20, and 29, 32-37 are submitted for instant examination.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/440/120 and 60/465754, fails to provide adequate support or enablement in the manner provided by the first paragraph of

35 U.S.C. 112 for one or more claims of this application. The instant claims recite a product of skin care, however, there is no support in the original disclosure of the provisional applications of this product as such.

Accordingly, the related claims will be examined according to the filing date of the instant application which is 1/15/2004

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 5, 6, 8, 9, 16, 29, 30, are rejected under 35 U.S.C. 102(b) as being anticipated by Zarif et al. WO0152817 (Zarif), the reference is provided in the IDS dated 07/01/2005.

Zarif teaches a cochleate containing a fragile nutrient (vitamin A, fatty acids, medicaments, flavors), charged lipid (phosphatidylserine) and a multivalent cation (calcium or zinc) additionally with a pharmaceutically accepted carrier. The composition contains vitamin A and can be formulated into a food. The molecules to be administered via the oral route.

5. Claims 1, 5, 6, 8, 9, 13-18, 29-30 and 35-37 rejected under 35 U.S.C. 102(b) as being anticipated by Mannino et al. WO9730725 (Mannino) provided by Applicant in IDS dated 07/01/2005.

Mannino describes a cochleate containing a fragile nutrient (vitamin A, fatty acids, medicaments, flavors), charged lipid (phosphatidylserine) and a multivalent cation (calcium) additionally with a pharmaceutically accepted carrier. The composition contains vitamin such as vitamins A, D, E or K (claims 1, 4, 5, 7, 9, 13-2, examples 8, 9, page 3 paragraph 1-page 11

paragraph 4, page 14 paragraph 7, page 22 paragraph 2). The cochleates can also be incorporated into consumable food preparations and also can be simply a drink (example 8). The method recited in claims 29, 32 and 35-37 is a method of administring wherein administering is an inherent act for a food or drink as disclosed by Mannino.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-10, 13-16, 19-20, and 29, 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mannino et al. WO9730725 (Mannino) in view of Mannino et al. US 20040146551 (Mannino 551).

Mannino has been relied upon for the reasons set forth hereinabove.

Mannino is silent towards the beta-carotene, the amount of the fragile nutrient, the soy phosphatidylserine and the skin product.

Mannino 551 teaches present invention provides new delivery vehicles for cargo moieties that are stable and capable of delivering desired amounts of active agent. The composition contains cochleate [136]. A fragile nutrient beta-carotene [0048] in an amount of

3% (example 5), a negatively charged lipid comprising soy phosphatidylserine, [0067]. The formulations can include delivery vehicles products, such as skin care [0097].

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the beta-carotene because Mannino teaches the generic use of vitamin A, it is within the abilities of the artisan to try between the finite number of the species included by generic vitamin A. Further, it is deemed obvious to a person of ordinary skill in the art to use an amount of 3% of beta-carotene disclosed by Mannino 551 and optimize this amount because the amount of a specific ingredient in a composition is a result of effective parameter that a person of ordinary skill in the art would routinely optimize. It would have been obvious to the person of ordinary skill to use soy phosphatidylserine because Mannino 551 teaches that an advantage of the vehicles of the present invention is the stability and safety of the composition, particularly when soy-based lipids are employed [0089]. These ingredients would give acceptable expectations to the person of ordinary skill in the art of success in producing a skin care product comprising fragile nutrient cochleat formulation containing a negatively charged phosphatidyl serine, beta-carotene and a divalent cation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thonngton, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-10, 13-16, 19-20, and 29, 32-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 2, 6, and 7 of U.S. Patent No. 5994318 in view of Mannino et al. US 20040146551 (Mannino 551). Although the conflicting claims are not identical, they are not patentably distinct from each other because '318 recites a nutrient and cochleate formulation comprising a divalent cation, a lipid, a fatty acid, and vitamins A and D. '318 claims do not recite the use of soy phosphatidylserine.

'551 teaches the use of soy phosphatidylserine percentages of fragile nutrient and the skin care products.

It would have been obvious to one of ordinary skill in the art to use soy phosphatidylserine because '551 discloses that teaches that an advantage of the vehicles of the present invention is the stability and safety of the composition, particularly when soy-based lipids are employed [0089].

5. Claims 1-10, 13-16, 19-20, and 29, 32-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 33 and 34 of U.S. Patent No. 6,592,894 in view of Mannino '551. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in said patent are product by process claims and instant generic claims thus, include the product by specific process claimed in said patent. Mannino '551 is relied upon for the use of soy phosphatidylserine percentages of ingredients and the skin care products.

8. Claims 1-10, 13-16, 19-20, and 29, 32-37 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 15, 16, 23 of copending Application No. 10/421358 in view of Mannino '551.

'358 recites cochleate composition comprising a negatively charged lipid such as phosphatidylserine, a divalent cation and vitamin A. Mannino '551 is relied upon for the use of soy phosphatidylserine percentages of ingredients and the skin care products.

This is a provisional obviousness-type double patenting rejection.

Simmilarly, claims 1-10, 13-16, 19-20, and 29, 32-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims applications 11/040615, 10/701364. Because of the big number of applications and patents wherein the scope of the claims overlap with the instant claims. The Examiner explained above the grounds of these rejections, Applicant has the burden to show otherwise.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618